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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/443,542	11/19/1999	FARZAN RASTINEJAD	PC10228A	7363
23913	7590	06/15/2005	EXAMINER	
PFIZER INC			MITCHELL, GREGORY W	
150 EAST 42ND STREET			ART UNIT	PAPER NUMBER
5TH FLOOR - STOP 49				
NEW YORK, NY 10017-5612			1617	

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/443,542	RASTINEJAD ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Gregory W. Mitchell	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 21 March 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 26-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 26-35 is/are rejected.
- 7) Claim(s) 26 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____.   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>03/21/05</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

This Office Action is in response to the Remarks filed March 21, 2005. Claims 26-35 are pending and are examined herein.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Declaration***

The Declaration under 37 CFR 1.132 filed March 21, 2005 is not considered because it has not been executed (it has not been signed).

### ***Claim Objections Maintained***

Claim 26 stands objected to because of the following informalities: it is terminated with a closed parenthetical; there is no open parenthetical in the claim. Appropriate correction is required.

### ***35 USC § 112 Rejection Maintained***

Claims 26-35 stand rejected under 35 USC 112(1) as failing to comply with the WRITTEN DESCRIPTION requirement for the reasons set forth in the Office Action dated September 22, 2004.

It is pointed out that the rejection is directed to step (b) of claim 26. Step (b) states that the action taken is: "permitting said stabilized protein to interact with one or more macromolecules that participates in a wild-type activity of said protein." As stated

Art Unit: 1617

in the previous Office Action, the rejection is made because Applicant does not describe how such a step is to occur, not because compound X would not function in such a step. Examiner has stipulated that Applicant has set forth an *in vivo* example in Example 4 on pages 49-50, but in said example, Applicant has only set forth that (1) a dosage was administered intraperitoneally, followed by (2) sacrifice of the animal. Clearly the administration step satisfies the written description of step (a) of claim 26, but there is no written description in Example 4 of what step (b) entails.

***35 USC § 112 Rejection Maintained***

Claims 26-35 stand rejected under 35 USC 112(1) as failing to **ENABLE** the entire **SCOPE** of the claimed invention for the reasons set forth in the Office Action dated September 22, 2004.

Applicant argues, "Applicant's competitor immediately and extensively validated the present invention and its applicability to drug discovery." This argument is not persuasive because Applicant is not claiming a method of drug discovery, but is claiming a method of treatment.

Applicant further argues, "It is thus clearly apparent that those skilled in the art have recognized that the teachings of the present invention are directed to valuable medical technology which has now been embraced for the very purpose taught by the claims solicited herein, for the treatment of cancer and for the discovery of additional organic compounds that can correct defective p53 under physiological conditions in patients." This argument is not persuasive because, again, the claimed invention is not

directed to a method of discovery of the compounds that can correct defective p53 under physiological conditions in patients, but to a method of treatment. Applicant further argues that one having ordinary skill in the art would be provided with ample guidance to select and identify the appropriate non-peptide compound to practice the claimed method without undue experimentation. This argument is not persuasive because Examiner has not made a total lack of enablement rejection, but a scope of enablement rejection. The basis of the 35 USC 112(1) scope of enablement rejection is that the skilled artisan would be burdened by undue experimentation to practice the **full scope** of Applicant's invention because the compounds claimed and encompassed by the term "organic non-peptide compound" are countless. Accordingly, the skilled artisan would be testing compounds indefinitely in order to fully realize and be capable of utilizing the full scope of Applicant's claimed invention.

Applicant's arguments that Examiner has not explained why he doubts the truth or accuracy of any statement in a supporting disclosure and backed up the assertions with acceptable evidence or reasoning is not persuasive for the same reasons as set forth above. Examiner has rejected the pending claims as being directed to a "genus" of compounds so large that it would take an indeterminable amount of time in order for the skilled artisan to use the full scope of Applicant's claimed invention. The clear reasoning for this allegation is that the phrase "organic non-peptide compound" literally encompasses *countless* variations.

Applicant's arguments that a specification may be enabling even if it requires a "considerable amount" of experimentation, that the broadest invention is supported by

the specification, and that the claims need not be limited to exemplified or preferred embodiments in order to satisfy enablement requirements are not persuasive. Again, it is Examiner's position that the amount of experimentation required to practice the full scope of Applicant's invention is not "considerable" but is undue. The broadest invention encompasses any "organic non-peptide compound". Furthermore, Applicant has mischaracterized Examiner's rejection by alleging that Examiner has limited Applicant to exemplified or preferred embodiments of the invention. Examiner does not purport to limit Applicant's invention to the specific *compounds* disclosed, but has limited the Applicant to the genus of compounds disclosed, structurally, by the specification.

Applicant's arguments regarding issued patents are not persuasive because issued patents are not subject to commentary by Examiner.

Applicant argues, "The fact that numerous compounds may be inoperative is irrelevant in view of the arguments presented above." This argument is not persuasive because *most* "organic non-peptide compounds" are *not* anti-cancer agents. Accordingly, not only will *numerous* compounds be inoperative, but *most* compounds encompassed by the instant claims will be inoperative.

### ***35 USC § 103 Rejection Maintained***

Claims 26-35 stand rejected under 35 USC 103 as being obvious over Barker (USPN 5616582) in view of both Yaish et al. (*Science*, 1988, 242, 933) and Lee et al.

(UPSN 5532220) for the reasons set forth in the Office Action dated September 22, 2004.

Applicant argues that the rejection amounts to "connecting the dots". This argument is not persuasive because Examiner has been forced to rely on Yaish et al. and Lee et al. *only* to show that the treatment taught in Barker meets the claims as instantly claimed.

Applicants arguments that the rejection fails because "the Barker compounds function by blocking kinase activation/signaling via the ATP binding domain of the EGF receptor" and that "there is neither any suggestion or statement, other than by the Examiner, that such compound bind to p53- nor do they." This argument is not persuasive because the compounds taught by Barker are within the scope of compounds disclosed by Applicant to meet the instant definition of "organic non-peptide compounds". Accordingly, absent evidence to the contrary, it is Examiner's position that the compounds disclosed by Barker meet the instant claims. Furthermore, Examiner does not understand Applicant's arguments. Applicant appears to be admitting on the record that compounds disclosed by Applicant as a preferred group of organic non-peptide compounds (i.e. compounds encompassed by group (I)) are non-functional in the instant invention.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER